



Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
Analytical Test Report (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Product Code	350000089	Specification Id	R0-350000089-00
Manufacturer	Dr.Reddy's Laboratories Ltd(CTO Uni	A.R. No.	F02RM13000030
Supplier	Vijayasri Organics Limited	Batch Size	10.000 KG
Mfg. Date	05/2013	Batch No.	FBGA00339
Exp. Date	--	Sampling Quantity	0.194 KG

S. No.	TEST	RESULT	SPECIFICATION
1	Appearance	A pale yellow ,crystalline powder slightly hygroscopic.	A pale yellow ,crystalline powder slightly hygroscopic.
2	Solubility	Soluble in water, slightly soluble in methanol, very slightly soluble in anhydrous ethanol. Practically insoluble in acetone, in ethyl acetate and in methylene chloride.	Soluble in water, slightly soluble in methanol, very slightly soluble in anhydrous ethanol. Practically insoluble in acetone, in ethyl acetate and in methylene chloride.
3	Identification		
3.1	IR	The infrared absorption spectrum of the sample in potassium bromide dispersion exhibits maxima only at the same wavelengths as that of a similar preparation of ciprofloxacin hydrochloride WS/RS.	The infrared absorption spectrum of the sample in potassium bromide dispersion exhibits maxima only at the same wavelengths as that of a similar preparation of ciprofloxacin hydrochloride WS/RS.
3.2	Reaction of Chlorides	The filter paper impregnated with diphenylcarbazine solution R turns violet-red.	The filter paper impregnated with diphenylcarbazine solution R turns violet-red.
4	Appearance of Solution	The solution is clear and	The solution is clear and not more

Remarks: APPROVED (Sample Conforms to above Specification)			
Checked By	Rajesh Kumar.Alubilli (LIMS Administrator)	Approved By	Ajay.Bhushod (LIMS Administrator)
Checked On	09-05-2013 20:47	Approved On	09-05-2013 20:50
Copy No.: N/A		Page No.: 1 of 2	
Note : This document has been generated electronically and is valid without signature.			
Format No.FTCQA062/F02-02			

Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
Analytical Test Report (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Product Code	350000089	Specification Id	R0-350000089-00
Manufacturer	Dr.Reddy's Laboratories Ltd(CTO Uni	A.R. No.	F02RM13000030
Supplier	Vijayasri Organics Limited	Batch Size	10.000 KG
Mfg. Date	05/2013	Batch No.	FBGA00339
Exp. Date	--	Sampling Quantity	0.194 KG

		not more intensely coloured than reference solution GY5.	intensely coloured than reference solution GY5.
5	pH	4.04	pH of solution is between 3.5 and 4.5
6	Impurity A (Floroquinolonic acid by TLC)	Not more than 0.2 %	Not more than 0.2 %
7	Related Substances by HPLC		
7.1	Ciprofloxacin Impurity C	0.03 %	Not more than 0.2%
7.2	Ciprofloxacin Impurity D	Below Disregard Limit	Not more than 0.2%
7.3	Chloroanalog	Not Detected	Not more than 0.06%
7.4	Maximum Unknown Individual Impurity	Below Disregard Limit	Not more than 0.06%
7.5	Total Impurities	0.05 %	Not more than 0.5%
8	Heavy Metals	Less than 20 ppm	Not more than 20 ppm
9	Water	6.3 %	Not more than 6.7 %
10	Sulfated Ash	0.01 %	Not more than 0.1%
11	Assay by HPLC	99.2 %	Not less than 98.0% and not more than 102.0% of Ciprofloxacin hydrochloride (C ₁₇ H ₁₉ CLFN ₃ O ₃ , H ₂ O)


Test Plan Remarks:

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Rajesh Kumar.Alubilli (LIMS Administrator)	Approved By	Ajay.Bhushod (LIMS Administrator)
Checked On	09-05-2013 20:47	Approved On	09-05-2013 20:50
Copy No.: N/A		Page No.: 2 of 2	

Note : This document has been generated electronically and is valid without signature.

Format No.FTCQA062/F02-02

Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
RAW DATA SHEET (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

1) Test Name: Appearance

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	07-05-2013 18:12	Next Calibration Date	08-05-2013 00:00
Instrument Usage Code	10000050	Used By	Rajesh Kumar.Alubilli
Used From	07-05-2013 20:16	Used Upto	07-05-2013 20:17
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	Weight (g)(EDAP01)	1.02121	

Refer GTP No. : GP004

Procedure:

1.02121 g. (EDAP01) of sample spread on white surface in a thin layer and observed the description under laboratory light conditions.

Q1	A pale yellow ,crystalline powder slightly hygroscopic.
Q2	Does Not Complies.
Observation: (EWS201) :Q1	
Special Observation: (EWS202) :	
Pass / Fail Status: (of Special Observation)(EWS203) :	

OBSERVED QUALITY: A pale yellow ,crystalline powder slightly hygroscopic.

PASS LIMIT DESCRIPTION: A pale yellow ,crystalline powder slightly hygroscopic.

RESULT: **Pass**

1	Tested By	Rajesh Kumar. Alubilli	07-05-2013 20:18	---
2	Accepted By	Ajay.Bhushod	09-05-2013 20:50	---

2) Test Name: Solubility

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	08-05-2013 10:48	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	10000054	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 11:16	Used Upto	08-05-2013 11:24
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	Weight1 (g)(EDAP02)	1.008	

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 1 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

RAW DATA SHEET
(Raw Material)
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Gross Wt.

1.00848

Tare Wt.

0.00009

Net Wt.

1.008

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	08-05-2013 10:48	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	10000055	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 11:39	Used Upto	08-05-2013 11:43
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
2	Weight2 (g)(EDAP03)	0.051	
Gross Wt.	Tare Wt.	Net Wt.	
0.05119	0.00000	0.051	

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	08-05-2013 10:48	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	10000058	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 15:41	Used Upto	08-05-2013 15:48
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
3	Weight3 (g)(EDAP04)	0.006	
Gross Wt.	Tare Wt.	Net Wt.	
0.00572	0.00004	0.006	

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	08-05-2013 10:48	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	10000059	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 15:59	Used Upto	08-05-2013 16:02
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
4	Weight4 (g)(EDAP05)	0.005	
Gross Wt.	Tare Wt.	Net Wt.	
0.00525	0.00002	0.005	

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	08-05-2013 10:48	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	10000062	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 17:12	Used Upto	08-05-2013 17:13
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	

Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 2 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

RAW DATA SHEET
 (Raw Material)

Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

5 Weight5 (g)(EDAP06) 0.005

Gross Wt.	Tare Wt.	Net Wt.
0.00520	0.00016	0.005

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	08-05-2013 10:48	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	10000063	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 17:13	Used Upto	08-05-2013 17:16
Mode	Inst. Conn.	Reasons	

S.No.	Field Desc.	Field Value
6	Weight6 (g)(EDAP07)	0.006

Gross Wt.	Tare Wt.	Net Wt.
0.00564	0.00000	0.006

Work Sheet Fields

Chemical Name: Methanol (RANKEM)			
Batch No	P13C100551	Expiry Date	25-04-2014
Qty. Value	50 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 01, W.S. Value: M027513001/1/1 (New Usage), Comments: --			

Chemical Name: Ethanol			
Batch No	20120828	Expiry Date	20-04-2015
Qty. Value	50 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 02, W.S. Value: 64-17-513001/1/3 (New Usage), Comments: --			

Chemical Name: Acetone (standard)			
Batch No	SE2SF62094	Expiry Date	22-04-2014
Qty. Value	50 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 03, W.S. Value: Acetone13001/1/1 (New Usage), Comments: --			

Chemical Name: Ethyl acetate (MERCK)			
Batch No	1F21F62283	Expiry Date	31-05-2013
Qty. Value	50 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 04, W.S. Value: 141-78-513001/1/1 (New Usage), Comments: --			

Chemical Name: Methylene chloride			
Batch No	1F21F62348	Expiry Date	15-05-2014
Qty. Value	50 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 05, W.S. Value: 75-09-313001/1/1 (New Usage), Comments: --			

Refer GTP No. : GP214

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 3 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

RAW DATA SHEET (Raw Material)

Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

In Water:**Procedure:**

1.008 g (EDAP02) of sample weighed into a stoppered test tube, added **25** mL (EWS01) quantity of water, shaken for **2** minutes (EWS02) on cyclomixer.

The solution was **Clear** (clear / not clear) (EWS03)

If it is not clear :

Again sonicated for **NA** minutes (EWS04) and shaken for another **NA** minutes (EWS05) and finally observed the solution.

The solution is **Clear** (clear / not clear) (EWS06)

Observation: **Soluble** (Soluble / Insoluble) (EWS10)

Interpretation: **Complies** (Complies/ does not complies) (EWS07)

In Methanol :**Procedure:**

0.051 g (EDAP03) of sample weighed into a stoppered test tube, added **50** mL (CHQTY01) quantity of Methnol shaken for **2** minutes (EWS08) on cyclomixer.

The solution was **Not Clear** (clear / not clear) (EWS09)

If it is not clear :

Again sonicated for EWS11 : **5** minutes and shaken for another EWS12 : **2** minutes and finally observed the solution.

The solution was **Clear** (clear / not clear) (EWS13)

Observation: **Soluble** (Soluble / Insoluble) (EWS31)

The


Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 4 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
RAW DATA SHEET (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Interpretation: **Complies** (Complies/ does not complies) (EWS14)

In Anhydrous Ethanol:

Procedure:

0.006 g (EDAP04) of sample weighed into a stoppered test tube, added **50** mL (CHQTY02) quantity of Anhydrous Ethanol, shaken for **2** minutes (EWS15) on cyclomixer.

The solution was **Not Clear** (clear / not clear) (EWS16).

If it is not clear:

Again sonicated for **5** minutes (EWS17) and shaken for another **2** minutes (EWS18) and finally observed the solution.

The solution was **Clear** (clear / not clear) (EWS19)

Observation: **Soluble** (Soluble / Insoluble) (EWS20)

Interpretation: **Complies** (Complies/ does not complies) (EWS21)


In Acetone:

Procedure:

0.005 g (EDAP05) of sample weighed into a stoppered test tube, added **50** mL (CHQTY03) quantity of Aceton shaken for **2** minutes on cyclomixer.

The solution was **not clear**

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 5 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
RAW DATA SHEET (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Old Value:clear	Reasons:typo error	Changed By:Rajesh Kumar. Alubilli 08-05-2013 16:11
-----------------	--------------------	----------------------------------------------------

(clear / not clear) (EWS23)

If it is not clear :

Again sonicated for 5 minutes (EWS24) and shaken for another 2 minutes (EWS25) and finally observed the solution.

The solution is **not clear** (clear / not clear) (EWS26)

Observation: **Insoluble** (Soluble / Insoluble) (EWS27)

Interpretation: **Complies** (Complies/ does not complies) (EWS28)

In Ethyl acetate :

Procedure:

0.005 g (EDAP06) of sample weighed into a stoppered test tube, added 50 mL (CHQTY04) quantity of Ethyl acetate shaken for 2 minutes (EWS29)on cyclomixer.

The solution was **Not clear** (clear / not clear) (EWS30)

If it is not clear :


Again sonicated for 5 minutes (EWS32) and shaken for another 2 minutes (EWS33) and finally observed the solution.

The solution is **not clear** (clear / not clear) (EWS34).

Observation: **Insoluble** (Soluble / Insoluble) (EWS35)

Interpretation: **Complies** (Complies/ does not complies) (EWS36)

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 6 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
RAW DATA SHEET (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

In Methylene chloride:

Procedure:

0.006 g (EDAP07) of sample weighed into a stoppered test tube, added 50 mL (CHQTY05) quantity Methylene shaken for 2 minutes (EWS37) on cyclomixer.

The solution was **not clear** (clear / not clear) (EWS38)

If it is not clear :

Again sonicated for 5 minutes (EWS39) and shaken for another 2 minutes (EWS40) and finally observed the solution.

The solution was **not clear** (clear / not clear) (EWS41)

Observation: **insoluble** (Soluble / Insoluble) (EWS42)

Interpretation: **Complies** (Complies/ does not comply) (EWS43)

Q1	Soluble in water, slightly soluble in methanol, very slightly soluble in anhydrous ethanol. Practically insoluble in acetone, in ethyl acetate and in methylene chloride.
Q2	Does Not Complies.
Observation: (EWS204) :Q1	
Special Observation: (EWS205) :	
Pass / Fail Status: (of Special Observation)(EWS206) :	

OBSERVED QUALITY: Soluble in water, slightly soluble in methanol, very slightly soluble in anhydrous ethanol. Practically insoluble in acetone, in ethyl acetate and in methylene chloride.


PASS LIMIT DESCRIPTION: Soluble in water, slightly soluble in methanol, very slightly soluble in anhydrous ethanol. Practically insoluble in acetone, in ethyl acetate and in methylene chloride.

RESULT: **Pass**

1	Tested By	Rajesh Kumar. Alubilli	08-05-2013 17:32	---
2	Accepted By	Ajay.Bhushod	09-05-2013 20:50	---

3) Test Name: Identification

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 7 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
RAW DATA SHEET (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	09-05-2013 14:25	Next Calibration Date	10-05-2013 00:00
Instrument Usage Code	10000074	Used By	Rajesh Kumar.Alubilli
Used From	09-05-2013 15:01	Used Upto	09-05-2013 15:06
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	Weight1 (g)(EDAP08)	1.27	
	Gross Wt.	Tare Wt.	Net Wt.
	1.27	0.00	1.27
2	Weight2 (g)(EDAP09)	325.62	
	Gross Wt.	Tare Wt.	Net Wt.
	325.62	0.00	325.62

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	09-05-2013 14:25	Next Calibration Date	10-05-2013 00:00
Instrument Usage Code	10000075	Used By	Rajesh Kumar.Alubilli
Used From	09-05-2013 15:09	Used Upto	09-05-2013 15:11
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	Qty Value(WSQTY01 Product/Material:Ciprofloxacin Hydrochloride Ph. Eur.(350000089) Container No.: W.S.LOT1300002/1)	1.62	

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	09-05-2013 14:25	Next Calibration Date	10-05-2013 00:00
Instrument Usage Code	10000076	Used By	Rajesh Kumar.Alubilli
Used From	09-05-2013 15:46	Used Upto	09-05-2013 15:50
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
3	Weight4 (g)(EDAP11)	0.1008	
	Gross Wt.	Tare Wt.	Net Wt.
	0.10080	0.00000	0.1008

Work Sheet Fields

Working Standard Name: Ciprofloxacin Hydrochloride Ph. Eur.(350000089)			
W.S. Lot No.	W.S.LOT1300002	Expiry Date	01-05-2014
Qty. Value	1.62 mg	Purity	93.6 %
Other Information: Sample Reference No.: F02RM13000030, Container Valid Upto: 09-05-2013 W.S. Field: Working Standard-01, W.S. Value: W.S.LOT1300002/1/005 (New Usage), Comments:			

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 8 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

RAW DATA SHEET
(Raw Material)
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Chemical Name: Potassium Bromide (Merck)

Batch No	1F2EC2021	Expiry Date	01-05-2015
Qty. Value	350 mg	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 01, W.S. Value: 858483313001/1/1 (New Usage), Comments: --			

Chemical Name: Diphenylcarbazide

Batch No	61780500251046	Expiry Date	07-11-2013
Qty. Value	0.20152 g	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 02, W.S. Value: 25648513001/1/1 (New Usage), Comments: --			

Chemical Name: Acetic Acid (Glacial)

Batch No	20120828	Expiry Date	02-02-2015
Qty. Value	10 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 03, W.S. Value: 64-19-713001/1/2 (New Usage), Comments: --			

Chemical Name: Ethanol

Batch No	1HFE2563	Expiry Date	01-05-2014
Qty. Value	100 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 04, W.S. Value: 64-17-513002/1/1 (New Usage), Comments: --			

Chemical Name: Potassium Dichromate

Batch No	112403J	Expiry Date	30-06-2015
Qty. Value	0.20705 g	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 05, W.S. Value: 1.02403.008013001/1/2 (New Usage), Comments: --			

Chemical Name: Sulfuric Acid

Batch No	1SEF21530	Expiry Date	03-05-2014
Qty. Value	1 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 06, W.S. Value: CE2C62028713001/1/4 (New Usage), Comments: --			

Instrument Name: Hot Air Oven(32HAO-12)

Calibrated On	09-05-2013	Calibration Due Date	19-06-2013
Used From	08-05-2013 08:00	Used UpTo	09-05-2013 08:00
Other Information: Used For: Drying, Sample Reference No.: F02RM13000030 W.S. Field: Oven ID 01, W.S. Value: 10000080 (New Usage), Comments:			

Instrument Name: IR Spectrophotometer(32FTI-02)

Calibrated On	03-05-2013	Calibration Due Date	03-11-2013
Used From	09-05-2013 11:00	Used UpTo	09-05-2013 11:30
Other Information: Used For: Identification, Sample Reference No.: F02RM13000030 W.S. Field: FTIR Spectrophotometer 01, W.S. Value: 10000078 (New Usage), Comments:			

Instrument Name: KBr Press(32KBR-02)

Calibrated On	09-05-2013	Calibration Due Date	01-10-2013
---------------	------------	----------------------	------------

Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 9 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

RAW DATA SHEET (Raw Material)

Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Used From	09-05-2013 11:00	Used UpTo	09-05-2013 14:00
Other Information: Used For: Identification , Sample Reference No.: F02RM13000030 W.S. Field: KBr Press ID No 01, W.S. Value: 10000081 (New Usage), Comments:			

Instrument Name: Muffle Furnace(32MUF-02)			
Calibrated On	09-05-2013	Calibration Due Date	19-06-2013
Used From	09-05-2013 08:00	Used UpTo	09-05-2013 09:00
Other Information: Used For: Drying of KBr , Sample Reference No.: F02RM13000030 W.S. Field: Oven ID 02, W.S. Value: 10000079(New Usage), Comments:			

A) By IR:

Refer GTP No.: GP160

Potassium Bromide Dried at: 250°C(EWS44) In Date, Time : 09-05-2013, 08:00(EWS45) Out Date, Time: 09-05-2013, 09:00(EWS46)

Ciprofloxacin Hydrochloride Ph.Eur In Date , Time : 08-05-2013, 09:00(EWS47) Out Date, Time: 09-05-2013, 09:00(EWS48)

Ciprofloxacin Hydrochloride RS /WS, Individual container samples, pool sample are dried at EWS49 : 103°C for EWS50 : 24 hours. Cooled in a desiccator from 09:00(EWS51) to 09:30 hours (EWS52).

Standard Preparation:

1.62mg (WSQTY01) of Ciprofloxacin Hydrochloride RS /WS triturated with 350mg (CHQTY06) of Potassium Bromide. Grinded the mixture, spread it uniformly in a die and compressed at a pressure of 800Mpa (EWS53).

Test Preparation:**Individual Container Identification :**

S.No.	Container No.	Wt of the sample taken (In mg)	Wt of Potassium Bromide taken (In mg)	Observation: Complies / Does not comply
1.	1(EWS54)	1.27(EDAP08)	325.62(EDAP09)	Complies(EWS55)

Procedure:

Recorded the spectrum of the Standard preparation, Individual container Identification preparation, over the range from 4000(EWS57) to 650cm⁻¹ (EWS58).

Observation: The infrared absorption spectrum of the sample in potassium bromide dispersion Exhibits(EWS59) (Exhibits / does not exhibits) maxima only at the same wavelength as that of a similar preparation of Ciprofloxacin Hydrochloride RS or WS.

Reaction of Chlorides:


Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 10 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
RAW DATA SHEET (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

<p>Diphenylcarbazide solution R:</p> <p>Dissolved 0.20152g (CHQTY08) of Diphenylcarbazide in 10ml (CHQTY09) of Glacial acetic acid and diluted to 100ml (CHQTY10) with Ethanol.</p> <p>Procedure:</p> <p>Weighed 0.1008g (EDAP11) of sample and transferred into a test tube. Added 0.20705g (CHQTY11) of potassium dichromate and 1mL (CHQTY12) of Sulfuric acid. Placed a filter paper strip impregnated with 0.1mL (EWS60) of diphenylcarbazide solution R over the opening of the test-tube.</p> <p>Interpretation: The paper Turns (turns / does not turn) (EWS61) violet to red.</p>

Sub Test-1: IR	
Q1	The infrared absorption spectrum of the sample in potassium bromide dispersion exhibits maxima only at the same wavelengths as that of a similar preparation of ciprofloxacin hydrochloride WS/RS.
Q2	Does Not Complies.
Observation: (EWS207) : Q1	
Special Observation: (EWS208) :	
Pass / Fail Status: (of Special Observation) (EWS209) :	

OBSERVED QUALITY: The infrared absorption spectrum of the sample in potassium bromide dispersion exhibits maxima only at the same wavelengths as that of a similar preparation of ciprofloxacin hydrochloride WS/RS.

PASS LIMIT DESCRIPTION: The infrared absorption spectrum of the sample in potassium bromide dispersion exhibits maxima only at the same wavelengths as that of a similar preparation of ciprofloxacin hydrochloride WS/RS.

RESULT: **Pass**

Sub Test-2: Reaction of Chlorides	
Q1	The filter paper impregnated with diphenylcarbazide solution R turns violet-red.
Q2	Does Not Complies.
Observation: (EWS210) : Q1	
Special Observation: (EWS211) :	
Pass / Fail Status: (of Special Observation) (EWS212) :	

OBSERVED QUALITY: The filter paper impregnated with diphenylcarbazide solution R turns violet-red.

PASS LIMIT DESCRIPTION: The filter paper impregnated with diphenylcarbazide solution R turns violet-red.


RESULT: **Pass**

FINAL RESULT: Pass

1	Tested By	Rajesh Kumar. Alubilli	09-05-2013 16:39	---
2	Accepted By	Ajay.Bhushod	09-05-2013 20:50	---

Modified Usage Record Details

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 11 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
RAW DATA SHEET (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Instrument Name:IR Spectrophotometer(32FTI-02)			
Calibrated On	03-05-2013	Calibration Due Date	03-11-2013
Used From	09-05-2013 11:00	Used UpTo	09-05-2013 11:30
Other Information: Used For: Identification test ,Sample Reference No.: F02RM13000030W.S. Value: 10000077(New Usage), Comments:			
Reasons:test, Changed By:Rajesh Kumar.Alubilli 09-05-2013 15:58			

4) Test Name: Appearance of Solution			
Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	08-05-2013 10:48	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	10000064	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 17:40	Used Upto	08-05-2013 17:43
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	Weight (g)(EDAP80)	0.504	
Gross Wt.	Tare Wt.	Net Wt.	
0.50356	0.00020	0.504	

Work Sheet Fields

Chemical Name:Stock Suspension Solution			
Batch No	R-13-01931	Expiry Date	27-05-2013
Qty. Value	1.5 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 01, W.S. Value: R-13-0193113001/1/2 (New Usage), Comments: --			
Chemical Name:Yellow Prime Solution			
Batch No	R-13-01013	Expiry Date	18-05-2013
Qty. Value	9.6 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 02, W.S. Value: R-13-0101313001/1/2 (New Usage), Comments: --			
Chemical Name:Red Prime Solution			
Batch No	R-13-01014	Expiry Date	18-05-2013
Qty. Value	0.2 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 03, W.S. Value: R-13-0101413001/1/2 (New Usage), Comments: --			
Chemical Name:Blue prime Solution			
Batch No	R-13-01020	Expiry Date	18-05-2013
Qty. Value	0.2 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 04, W.S. Value: R-13-0102013001/1/2 (New Usage), Comments: --			
Chemical Name:1% HCl Solution			
Batch No	R-13-01479	Expiry Date	09-06-2013
Qty. Value	1 mL	Sample Reference No.	F02RM13000030

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 12 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

RAW DATA SHEET
(Raw Material)
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Other Information: W.S. Field: [Chemical - 05](#), W.S. Value: [R-13-0147913001/1/2 \(New Usage\)](#), Comments: --**Chemical Name: 1% HCl Solution**

Batch No	R-13-01479	Expiry Date	09-06-2013
Qty. Value	97 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 06 , W.S. Value: R-13-0147913001/1/3(New Usage) , Comments: --			

Refer GTP No.: GP015 , GP081

Reference suspension preparation: **1.5** mL (*CHQTY07*) of the stock suspension preparation pipetted and transferred into a **100** mL (*EWS62*) volumetric flask and diluted to volume with water. Mixed **5** mL (*EWS63*) this suspension and **95** mL (*EWS64*) of water .

Mixed **9.6** mL (*CHQTY13*) Yellow primary solution, **0.2** mL (*CHQTY14*) Red primary solution, **0.2** mL (*CHQTY15*) Blue primary solution and **1** mL (*CHQTY16*) of 1 % hydrochloric acid. Mixed **3** mL (*EWS65*) of this solution with **97** mL (*CHQTY17*) of 1 % Hydrochloric acid.

Sample preparation (Solution S):

0.504 g (*EDAP80*) of sample weighed and transferred into a **20** mL (*EWS66*) of volumetric flask and dissolved in water and diluted to volume with water.

Sample preparation:

Diluted **10** mL (*EWS67*) of Solution S to **20** mL (*EWS68*) with carbon-dioxide free water.

Procedure:

For clarity: Filled the sample preparation and reference suspension preparation in flat bottomed test tubes to a depth of 40 mm. Compared the contents of the test tubes against a black back ground by viewing under diffused day light down the vertical axis of the tubes.

Printed by: [Ajay.Bhushod](#)

Printed on: 10-05-2013 19:13

Page No.: 13 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

RAW DATA SHEET
(Raw Material)
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

For colour: Filled the Sample preparation and reference color preparation in flat bottomed test tubes to a depth of 40 mm. Compared the contents of the test tubes against a black back ground by viewing under diffused day light down the vertical axis of the tubes.

Interpretation : The color produced in sample preparation is **not greater** (not greater) (EWS69) than reference solution(GY5).

Q1	The solution is cleare and not more intensely coloured than reference solution GY5.
Q2	Does Not Complies.
Observation: (EWS213) :Q1	
Special Observation: (EWS214) :	
Pass / Fail Status: (of Special Observation)(EWS216) :	

OBSERVED QUALITY: The solution is cleare and not more intensely coloured than reference solution GY5.
 PASS LIMIT DESCRIPTION: The solution is cleare and not more intensely coloured than reference solution GY5.
RESULT: Pass

1	Tested By	Rajesh Kumar. Alubilli	08-05-2013 18:07	---
2	Accepted By	Ajay.Bhushod	09-05-2013 20:50	---

5) Test Name: pH

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	08-05-2013 10:48	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	10000065	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 17:49	Used Upto	08-05-2013 17:51
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	Weight (g)(EDAP12)	0.548	
Gross Wt.	Tare Wt.	Net Wt.	
0.54895	0.00126	0.548	

Instrument Id	32PHM-21	Make	Thermo
Calibrated On	08-05-2013 11:05	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	10000066	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 17:59	Used Upto	08-05-2013 17:59
Mode	Inst. Conn.	Reasons	

Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 14 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

RAW DATA SHEET
(Raw Material)
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

S.No.	Field Desc.	Field Value
1	pH(EDAP25)	4.04

*GTP No.: GP292***Sample Preparation:**

Weighed **0.548g**(EDAP12)of sample and transferred into a **20mL**(EWS70)of volumetric flask and dissolved in water and diluted to volumewith water.

Determined pH of Sample preparation and noted.

S. No.	Variable	Symbol	TDS Symbol	Value(UOM)
1	pH	pH	EDAP25	4.04

FORMULA: (pH)

UOM (R):

No. Of Decimals: 2

Calculated Value: **4.04**

PASS LIMIT DESCRIPTION: pH of solution is between 3.5 and 4.5

RESULT: Pass

1	Tested By	Rajesh Kumar. Alubilli	08-05-2013 18:01	---
2	Accepted By	Ajay.Bhushod	09-05-2013 20:50	---

6) Test Name: Impurity A (Floroquinolonic acid by TLC)

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	08-05-2013 10:48	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	1000067	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 19:35	Used Upto	08-05-2013 19:36
Mode	Inst. Conn.	Reasons	

S.No.	Field Desc.	Field Value
1	Weight (mg)(EDAP13)	50.67

Gross Wt. Tare Wt. Net Wt.

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 15 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

RAW DATA SHEET
(Raw Material)
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

50.67 0.00 50.67

Work Sheet Fields

Chemical Name: Acetonitrile			
Batch No	1LMDERF	Expiry Date	02-05-2014
Qty. Value	10 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 01, W.S. Value: 67-64-213001/1/2 (New Usage) , Comments: --			

Chemical Name: Ammonia			
Batch No	AG1A610389	Expiry Date	04-04-2014
Qty. Value	20 L	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 02, W.S. Value: Ammonia13001/1/1 (New Usage) , Comments: --			

Chemical Name: Methanol (RANKEM)			
Batch No	P13C100551	Expiry Date	25-04-2014
Qty. Value	40 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 03, W.S. Value: M027513001/1/2 (New Usage) , Comments: --			

Chemical Name: Methylene chloride			
Batch No	1F21F62348	Expiry Date	15-05-2014
Qty. Value	40 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 04, W.S. Value: 75-09-313001/1/2 (New Usage) , Comments: --			

Chemical Name: Ammonia			
Batch No	AG1A610389	Expiry Date	04-04-2014
Qty. Value	45 L	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 05, W.S. Value: Ammonia13001/1/2 (New Usage) , Comments: --			

Chemical Name: Ammonia			
Batch No	AG1A610389	Expiry Date	04-04-2014
Qty. Value	50 L	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 06, W.S. Value: Ammonia13001/1/3 (New Usage) , Comments: --			

Ref.Standard Name: Ciprofloxacin Impurity-A			
Ref.Std. Lot No.	C2190050/13001	Batch No	4
Qty. Value	2.5 mg	Expiry Date	01-05-2014
Water Content	0	Potency	0
Other Information: Sample Reference No.: F02RM13000030 W.S. Field: Reference Standard-01 , W.S. Value: C2190050/13001/001(New Usage) , Comments:			

Mobile Phase preparation:Printed by: [Ajay.Bhushod](#)

Printed on: 10-05-2013 19:13

Page No.: 16 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

RAW DATA SHEET (Raw Material)

Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

10 mL (CHQTY18) Acetonitrile, 20 mL (CHQTY19) concentrated Ammonia, 40 mL (CHQTY20) Methanol and 40 mL (CHQTY21) Methylene chloride are mixed.

Stationary phase:

TLC plate coated with **Silicagel F2S4** (EWS71)

Load: 5 µL (EWS72)

Dilute Ammonia.:

Diluted 45 ml (CHQTY22) of ammonia to 100 ml (EWS73) with water.

Test solution:

50.67 mg (EDAP13) of sample weighed and transferred into a 5 mL (EWS74) of volumetric flask, dissolved and diluted to volume with purified water and mixed.

Reference solution:

2.5 mg (RSQTY01) of Ciprofloxacin impurity A CRS into a 25 mL (EWS75) volumetric flask dissolved in mixture of 0.1 mL (EWS76) of dilute ammonia R1 and 20 mL (EWS77) of purified water. Diluted to volume with purified water and mixed.

Pipetted 2 mL (EWS78) of the above solution into 10 mL (EWS79) volumetric flask, diluted to volume with purified water and mixed.

Procedure:

1) Applied separately to the plate 5 µL (EWS80) of Test solution and Reference solution to a thin layer

Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 17 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

RAW DATA SHEET
(Raw Material)
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

chromatographic plate.

2) Placed an evaporating dish containing **50** mL (CHQTY23) of concentrated Ammonia at the bottom of a chromatographic tank, closed and exposed the plate to the Ammonia vapor for **15** minutes (EWS81).

3) After **15** minutes (EWS82) withdraw and transferred to the above chromatographic chamber. Allowed the chromatogram to develop over a path of **15** cm (EWS83).

4) Removed the plate from developing chamber, mark the solvent front, and allowed the plate to air dry.

5) Examined the plate under ultraviolet light at **254** nm (EWS84).

Interpretation: Any spot corresponding to Impurity A in the chromatogram obtained with the test solution is **not more intense** (**not more intense / more intense**) (EWS85) than the spot in the chromatogram obtained with reference solution (0.2%).

Q1	Not more than 0.2 %
Q2	Does Not Complies.
Observation: (EWS217) :Q1	
Special Observation: (EWS218) :	
Pass / Fail Status: (of Special Observation)(EWS219) :	

OBSERVED QUALITY: **Not more than 0.2 %**

PASS LIMIT DESCRIPTION: Not more than 0.2 %


RESULT: Pass

1	Tested By	Rajesh Kumar. Alubilli	08-05-2013 19:42	---
2	Accepted By	Ajay.Bhushod	09-05-2013 20:50	---

7) Test Name: Related Substances by HPLC

Instrument Id	32PHM-21	Make	Thermo
Calibrated On	09-05-2013 14:25	Next Calibration Date	10-05-2013 00:00
Instrument Usage Code	10000082	Used By	Rajesh Kumar.Alubilli
Used From	09-05-2013 19:09	Used Upto	09-05-2013 19:15
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	pH(EDAP14)	3.25	

Printed by: Ajay.Bhushod**Printed on:** 10-05-2013 19:13**Page No.:** 18 of 35**Note :** This document has been generated electronically and is valid without signature.**Format No.**

Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
RAW DATA SHEET (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	09-05-2013 14:25	Next Calibration Date	10-05-2013 00:00
Instrument Usage Code	10000083	Used By	Rajesh Kumar.Alubilli
Used From	09-05-2013 19:17	Used Upto	09-05-2013 19:22
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	Weight (mg)(EDAP15)	50.76	
	Gross Wt.	Tare Wt.	Net Wt.
	50.76	0.00	50.76

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	09-05-2013 14:25	Next Calibration Date	10-05-2013 00:00
Instrument Usage Code	10000084	Used By	Rajesh Kumar.Alubilli
Used From	09-05-2013 19:22	Used Upto	09-05-2013 19:24
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	Qty Value(RSQTY02 Ref. Std Name: Ciprofloxacin Peak Identification Ref. Std Lot No.: Y0000199/13001)	5.56	

Work Sheet Fields

Chemical Name:Ortho-Phosphoric Acid			
Batch No	R082A13	Expiry Date	31-12-2014
Qty. Value	4.2 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 01, W.S. Value: 7664-38-213001/1/1 (New Usage), Comments: --			

Chemical Name:Acetonitrile			
Batch No	1LMDERF	Expiry Date	02-05-2014
Qty. Value	390 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 02, W.S. Value: 67-64-213001/1/3 (New Usage), Comments: --			

Chemical Name:Triethylamine			
Batch No	SE2E620289	Expiry Date	30-04-2014
Qty. Value	3 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 03, W.S. Value: 121-44-813001/1/3 (New Usage), Comments: --			

Ref.Standard Name:Ciprofloxacin Peak Identification			
Ref.Std. Lot No.	Y0000199/13001	Batch No	1.4
Qty. Value	5.56 mg	Expiry Date	06-05-2015
Water Content	1 %	Potency	100 %
Other Information: Sample Reference No.: F02RM13000030 W.S. Field: Reference Standard-01, W.S. Value: Y0000199/13001/001 (New Usage), Comments:			

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 19 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

RAW DATA SHEET (Raw Material)

Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Instrument Name: Sonicator(32SON-20)

Calibrated On	08-05-2013	Calibration Due Date	08-05-2014
Used From	09-05-2013 10:00	Used UpTo	09-05-2013 10:10

Other Information: Used For: For RS Test , Sample Reference No.: F02RM13000030 W.S. Field: Sonicator ID.No 01, W.S. Value: 10000085(New Usage), Comments:

Refer GTP No.: GP032

Liquid Chromatographic System:

Phosphoric acid (2.45 g/L H3PO4):

Diluted 4.2 mL (CHQTY24) of phosphoric acid to 3000 ml (EWS86) with water and adjusted to pH 3.25 (EDAP14) with 3 ml (CHQTY26) Triethylamine.

Mobile phase:

- 1) 390 mL (CHQTY25) of Acetonitrile, and 2610 mL (EWS87) of Phosphoric acid (2.45 g/L H3PO4) taken and mixed.
- 2) Filtered the above solution through 0.45 µm (EWS88) membrane filter.
- 3) Degassed in a Sonicator for 10 minutes (EWS89).

Reference solution (a):

5.56 mg (RSQTY02) of the Ciprofloxacin hydrochloride for peak identification CRS/WS accurately weighed and transferred into a 10 mL (EWS90) volumetric flask, dissolved and diluted to volume with the mobile phase and mixed.

Standard Solution (Reference solution (b)):

Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 20 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

RAW DATA SHEET
(Raw Material)
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Test solution)

50.76 mg (EDAP15) of the sample accurately weighed and transferred into a **100** mL (EWS91) volumetric flask, dissolved and diluted to volume with the mobile phase and mixed. Filtered through membrane filter.

Reference solution (b):

Diluted **1** mL (EWS93) of Test solution-I to **50** mL (EWS94) with the mobile phase. Diluted **1** mL (EWS95) of this solution to **10** mL (EWS96) with the mobile phase.

Procedure:

50 µL (EWS101) injected separately each of the mobile phase as Blank; the Reference solution (a), Reference solution (b)-I, Reference solution (b)-II, Test solution-I, Test solution-II and Reference solution(a) (as a bracketing resolution) into the liquid chromatography and the recorded the chromatograms.

Observation:

i) The Relative retention time of the Impurity C : **0.7** (EWS102)

ii) The Relative retention time of the Impurity D : **1.2** (EWS103)

Bracketing system suitability:

The resolution between the peaks due to impurity B and impurity C obtained from the Reference solution (B) is **2.285** (NLT 1.3) (EWS104).

Printed by: **Ajay.Bhushod**Printed on: **10-05-2013 19:13**Page No.: **21 of 35****Note : This document has been generated electronically and is valid without signature.****Format No.**

RAW DATA SHEET

(Raw Material)

Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Bracketing Standard: **Complies** (Complies / does not comply) (EWS105).System Suitability: **Complies** (Complies / does not comply) (EWS106)

S. No.	Variable	Symbol	TDS Symbol	Value(UOM)
1	Peak area of principal peak of Reference solution b.	S	EDAP26	227890
2	Peak area of Ciprofloxacin impurity C for Test solution.	C	EDAP27	55805
3	Peak area of Ciprofloxacin impurity D for Test solution.	D	EDAP28	7397
4	Peak area of Chloroanalog impurity for Test solution.	B	EDAP29	0
5	Area of any maximum unknown individual impurity, other than peak(s) due to imp.C, imp.D. Chloroanalog, principal peak, mobile phase for test Solution.	I	EDAP30	12707

Sub Test-1: Ciprofloxacin Impurity CFORMULA: $((C)/(S)) \times (0.2) \times (0.6)$

No. Of Decimals: 2

Calculated Value: 0.03 %

PASS LIMIT DESCRIPTION: Not more than 0.2%

RESULT: Pass**Sub Test-2: Ciprofloxacin Impurity D**FORMULA: $((D)/(S)) \times (0.2) \times (1.4)$

No. Of Decimals: 2

Calculated Value: 0.01 %

PASS LIMIT DESCRIPTION: Not more than 0.2%

RESULT: Pass**Sub Test-3: Chloroanalog**FORMULA: $((B) \times (0.2)) / (S)$

No. Of Decimals: 3

Calculated Value: 0.000 %

PASS LIMIT DESCRIPTION: Not more than 0.06%

RESULT: Pass**Sub Test-4: Maximum Unknown Individual Impurity**FORMULA: $((I) \times (0.2)) / (S)$

No. Of Decimals: 3

Calculated Value: 0.011 %

PASS LIMIT DESCRIPTION: Not more than 0.06%


Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 22 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
RAW DATA SHEET (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

RESULT: Pass
Sub Test-5: Total Impurities
 FORMULA: (R1)+(R2)+(R3)+(R4)
 No. Of Decimals: 2
 Calculated Value: 0.05 %
 PASS LIMIT DESCRIPTION: Not more than 0.5%
RESULT: Pass
FINAL RESULT: Pass

1	Tested By	Rajesh Kumar. Alubilli	09-05-2013 20:47	---
2	Accepted By	Ajay.Bhushod	09-05-2013 20:50	---

8) Test Name: Heavy Metals

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	09-05-2013 14:25	Next Calibration Date	10-05-2013 00:00
Instrument Usage Code	10000073	Used By	Rajesh Kumar.Alubilli
Used From	09-05-2013 14:42	Used Upto	09-05-2013 14:48
Mode	Inst. Conn.	Reasons	

S.No.	Field Desc.	Field Value
1	Weight (g)(EDAP17)	0.25115
	Gross Wt. Tare Wt. Net Wt.	
	0.25133 0.00018 0.25115	

Work Sheet Fields

Chemical Name:Lead Standard Solution			
Batch No	R-13-0626	Expiry Date	01-08-2013
Qty. Value	5 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 01, W.S. Value: R-13-0074113001/1/1 (New Usage), Comments: --			

Chemical Name:Buffer Solution pH 3.5 Reagent			
Batch No	R-13-00741	Expiry Date	01-08-2013
Qty. Value	2 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 02, W.S. Value: R-13-062613001/1/1 (New Usage), Comments: --			

Chemical Name:Thioacetamide			
Batch No	R-13-0740	Expiry Date	01-08-2013
Qty. Value	1.2 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 03, W.S. Value: R-13-074013001/1/1(New Usage), Comments: --			

Refer GTP No.: GP084

Test solution:

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 23 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

RAW DATA SHEET (Raw Material)

Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Dissolved **0.25115** g (EDAP17) of sample in purified water and diluted to **30** ml (EWS107) with the same solvent. Filtered the solution through **0.45** μ m (EWS108) membrane filter.

Procedure:

Diluted **5** ml (CHQTY27) of lead standard solution to **30** ml (EWS109) with water. Placed a membrane filter and above it a filter holder.

Prepared the filtration apparatus by adapting the barrel of a **50** mL (EWS110) syringe without its position. Transferred a portion of test solution into the syringe barrel, put the piston in place and then applied an even pressure on it until the whole of the liquid has been filtered. Removing the filter holder and checked that the membrane filter remains uncontaminated with impurities. Otherwise replaced the filter with a new one and repeated the operation.

To the prefilter or to the prescribed volume of the filtrate added **2** mL (CHQTY28) buffer solution pH 3.5 and **1.2** mL (CHQTY29) of thioacetamide reagent. Mixed and allowed to stand for **10** minutes (EWS111) opened the filter holder and inverted the order of the filters, taking care to avoid any external contamination so that the liquid first passed through the membrane filter before passing through the prefilter. Refixed it to the barrel of the syringe.

After **10** minutes (EWS112), transferred the whole solution into the syringe barrel, kept the piston in place and then filtered slowly by applying moderate and constant pressure on it until the whole of the liquid has been filtered. Then removed the filter holder, open it, carefully removed the membrane filter and dried using a dry filter paper. Treated the reference solution in the same manner as for test solution.

Interpretation: The color of the solution obtained with the test solution is **Not more intense** (*not more intense / more intense*) (EWS113) than that of the standard.

Q1	Less than 20 ppm
Q2	Does Not Complies
Observation: (EWS220) : Q1	
Special Observation: (EWS221) :	
Pass / Fail Status: (of Special Observation)(EWS222) :	

OBSERVED QUALITY: **Less than 20 ppm**

PASS LIMIT DESCRIPTION: Not more than 20 ppm

RESULT: Pass

1	Tested By	Rajesh Kumar. Alubilli	09-05-2013 15:00	---
2	Accepted By	Ajay.Bhushod	09-05-2013 20:50	---

9) Test Name: Water

Printed by: **Ajay.Bhushod**

Printed on: **10-05-2013 19:13**

Page No.: **24 of 35**

Note : This document has been generated electronically and is valid without signature.

Format No.

RAW DATA SHEET
 (Raw Material)

Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	07-05-2013 18:12	Next Calibration Date	08-05-2013 00:00
Instrument Usage Code	10000051	Used By	Rajesh Kumar.Alubilli
Used From	07-05-2013 20:19	Used Upto	07-05-2013 20:27
Mode	Inst. Conn.	Reasons	

S.No.	Field Desc.	Field Value
1	Weight (g)(EDAP18)	0.208
	Gross Wt. Tare Wt. Net Wt.	
	0.20775 0.00020 0.208	

Instrument Id	32KFA-07	Make	Metrohm
Calibrated On	07-05-2013 20:28	Next Calibration Date	08-05-2013 00:00
Instrument Usage Code	10000052	Used By	Rajesh Kumar.Alubilli
Used From	07-05-2013 20:31	Used Upto	07-05-2013 20:36
Mode	File Browsing	Reasons	

S.No.	Field Desc.	Field Value
1	% Water(%)(EDAP31)	6.3380

Document(s)

1.1.1) Ciprofloxacin Ph.Eur(F02RM13000030_196_2)

Work Sheet Fields

Chemical Name:Dried Methanol			
Batch No	SA3SF62858	Expiry Date	01-05-2014
Qty. Value	25 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 01, W.S. Value: 1.94800.052113001/1/3 (New Usage), Comments: --			

Chemical Name:Karl Fischer Regent			
Batch No	AHIAF61509	Expiry Date	01-05-2014
Qty. Value	3 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 02, W.S. Value: NA13001/1/3(New Usage), Comments: --			

Refer GTP No.: GP177

Weight of the sample taken 0.208 g (EDAP18).

S. No.	Variable	Symbol	TDS Symbol	Value(UOM)
1	% Water	W	EDAP31	6.3380%

Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 25 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

RAW DATA SHEET
(Raw Material)
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

FORMULA: (W)

UOM (R): %

No. Of Decimals: 1

Calculated Value: 6.3 %

PASS LIMIT DESCRIPTION: Not more than 6.7 %

RESULT: Pass

1	Tested By	Rajesh Kumar. Alubilli	07-05-2013 20:37	---
2	Accepted By	Ajay.Bhushod	09-05-2013 20:50	---

10) Test Name: Sulfated Ash

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	08-05-2013 10:48	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	10000068	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 19:53	Used Upto	08-05-2013 20:04
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	Weight1 (g)(EDAP19)	40.845	
	Gross Wt.	Tare Wt.	Net Wt.
	40.84495	0.00008	40.845
2	Weight2 (g)(EDAP20)	41.891	
	Gross Wt.	Tare Wt.	Net Wt.
	41.89147	0.00006	41.891

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	08-05-2013 10:48	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	10000069	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 20:09	Used Upto	08-05-2013 20:12
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
3	Weight3 (g)(EDAP21)	41.88	
	Gross Wt.	Tare Wt.	Net Wt.
	41.87965	0.00012	41.88

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	09-05-2013 14:25	Next Calibration Date	10-05-2013 00:00
Instrument Usage Code	10000070	Used By	Rajesh Kumar.Alubilli
Used From	09-05-2013 14:30	Used Upto	09-05-2013 14:30
Mode	Bypass Inst. Conn.	Reasons	Value Collected

Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 26 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

RAW DATA SHEET
(Raw Material)
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

S.No.	Field Desc.	Field Value
4	Weight4 (g)(EDAP22)	41.88
Gross Wt.	Tare Wt.	Net Wt.
41.88	0	41.88

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	09-05-2013 14:25	Next Calibration Date	10-05-2013 00:00
Instrument Usage Code	1000071	Used By	Rajesh Kumar.Alubilli
Used From	09-05-2013 14:31	Used Upto	09-05-2013 14:32
Mode	Bypass Inst. Conn.	Reasons	Value Collected

S.No.	Field Desc.	Field Value
4	Weight4 (g)(EDAP22)	40.85
Gross Wt.	Tare Wt.	Net Wt.
40.85	0	40.85

S.No	Field Symbol	Field New Value	Field Old Value	Modified By	Modified On	Reasons for Modification
4.1	EDAP22	40.85	41.88	Rajesh Kumar. Alubilli	09-05-2013 14:31	Typo Error

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	09-05-2013 14:25	Next Calibration Date	10-05-2013 00:00
Instrument Usage Code	1000072	Used By	Rajesh Kumar.Alubilli
Used From	09-05-2013 14:36	Used Upto	09-05-2013 14:38
Mode	Bypass Inst. Conn.	Reasons	Testing

S.No.	Field Desc.	Field Value
1	Weight1 (g)(EDAP19)	40.84516
Gross Wt.	Tare Wt.	Net Wt.
40.84516	0	40.84516
2	Weight2 (g)(EDAP20)	41.85518
Gross Wt.	Tare Wt.	Net Wt.
41.85518	0	41.85518
4	Weight4 (g)(EDAP22)	40.84527
Gross Wt.	Tare Wt.	Net Wt.
40.84527	0	40.84527

S.No	Field Symbol	Field New Value	Field Old Value	Modified By	Modified On	Reasons for Modification
5.1	EDAP19	40.84516	40.845	Rajesh Kumar. Alubilli	09-05-2013 14:35	Testing

Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 27 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

RAW DATA SHEET
(Raw Material)
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

5.2	EDAP20	41.85518	41.891	Rajesh Kumar. Alubilli	09-05-2013 14:35	Testing
5.3	EDAP22	40.84527	40.85	Rajesh Kumar. Alubilli	09-05-2013 14:35	Testing

Work Sheet Fields

Chemical Name: Sulfuric Acid			
Batch No	1SEF21530	Expiry Date	03-05-2014
Qty. Value	1 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 01, W.S. Value: CE2C62028713001/1/2 (New Usage), Comments: --			

Chemical Name: Sulfuric Acid			
Batch No	1SEF21530	Expiry Date	03-05-2014
Qty. Value	1 mL	Sample Reference No.	F02RM13000030
Other Information: W.S. Field: Chemical - 02, W.S. Value: CE2C62028713001/1/3 (New Usage), Comments: --			

W.S. Field: Muffle Furnace ID No 01, W.S. Value: 32MUF-02 (By-Passed), Comments: Used

Refer GTP No.: GP018

Empty Crucible ignited at : 600 °C (EWS114)

In Date, Time : 08-05-2013, 15:30 (EWS115) Out Date, Time: 08-05-2013, 16:00 (EWS116)

Crucible cooled to room temperature in desiccator from 16:00 to 16:30 hours (EWS117).

Weight of empty crucible (W1) : 40.84516 g (EDAP19).

Weight of crucible with sample before ignition (W2) : 41.85518 g (EDAP20).

41.88 g (EDAP21) of sample weighed in a crucible, Moisten the residue with 1 mL (CHQTY30) of Sulphuric Acid. Heated the crucible gently at low

temperature the substance is thoroughly charred and cooled, Moisten the residue with 1 mL (CHQTY31) of Sulphuric Acid.

Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 28 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

RAW DATA SHEET (Raw Material)

Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Heated the crucible gently

until white fumes no longer evolved. Ignited the crucible at a temperature **600 ° C** (EWS118) until the residue is completely incinerated.

*Ignited the crucible from **08-05-2013, 17:15** (EWS119) to **19:35 hrs** (EWS120).*

Allowed the crucible to cool (to room temperature) in a desiccator over silica gel, and weighed it again.

*Crucible cooled to room temperature in desiccator from **19:35 to 20:05 hrs** (EWS121)*

*Weight of crucible with sample after ignition (W_3) : **40.84527 g** (EDAP22).*

S. No.	Variable	Symbol	TDS Symbol	Value(UOM)
1	Weight of empty crucible	W1	EDAP19	40.84516g
2	Weight of crucible with sample before ignition	W2	EDAP20	41.85518 g
3	Weight of crucible with sample after ignition	W3	EDAP22	40.84527 g

FORMULA: $((W_3)-(W_1))*(100)/((W_2)-(W_1))$

UOM (R): %

No. Of Decimals: 2

Calculated Value: **0.01 %**

PASS LIMIT DESCRIPTION: Not more than 0.1%

RESULT: Pass

1	Tested By	Rajesh Kumar. Alubilli	09-05-2013 14:38	---
---	-----------	------------------------	------------------	-----


Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 29 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
RAW DATA SHEET (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

2	Accepted By	Ajay.Bhushod	09-05-2013 20:50	---
---	-------------	--------------	------------------	-----

11) Test Name: Assay by HPLC

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	07-05-2013 18:12	Next Calibration Date	08-05-2013 00:00
Instrument Usage Code	10000053	Used By	Rajesh Kumar.Alubilli
Used From	07-05-2013 21:40	Used Upto	07-05-2013 21:43
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	Weight of sample taken. (mg)(EDAP34)	50.71	
Gross Wt.	Tare Wt.	Net Wt.	
50.71	0.00	50.71	

Instrument Id	32PHM-21	Make	Thermo
Calibrated On	08-05-2013 11:05	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	10000057	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 14:41	Used Upto	08-05-2013 14:46
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	pH(EDAP23)	3.23	

Instrument Id	32BAL-39	Make	Sartorius
Calibrated On	08-05-2013 10:48	Next Calibration Date	09-05-2013 00:00
Instrument Usage Code	10000061	Used By	Rajesh Kumar.Alubilli
Used From	08-05-2013 16:35	Used Upto	08-05-2013 16:36
Mode	Bypass Inst. Conn.	Reasons	Value Collected
S.No.	Field Desc.	Field Value	
2	Weight (mg)(EDAP24)	50	
Gross Wt.	Tare Wt.	Net Wt.	
50.17	0.17	50	

S.No	Field Symbol	Field New Value	Field Old Value	Modified By	Modified On	Reasons for Modification
3.1	EDAP24	50	,	Rajesh Kumar. Alubilli	08-05-2013 16:35	Modified

Work Sheet Fields			
Working Standard Name: Ciprofloxacin Hydrochloride Ph. Eur.(350000089)			
W.S. Lot No.	W.S.LOT1300002	Expiry Date	01-05-2014
Qty. Value	46.8 mg	Purity	93.6 %

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 30 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

RAW DATA SHEET
(Raw Material)
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Other Information: Sample Reference No.: F02RM13000030, Container Valid Upto: 09-05-2013 W.S. Field: Working Standard-01, W.S. Value: W.S.LOT1300002/1/004 (New Usage), Comments:

Working Standard Name: Ciprofloxacin Hydrochloride Ph. Eur.(350000089)

W.S. Lot No.	W.S.LOT1300001	Expiry Date	26-07-2013
Qty. Value	0.05082 g	Purity	93.6 %

Other Information: Sample Reference No.: F02RM13000030, Container Valid Upto: 01-06-2013 W.S. Field: Working Standard-02, W.S. Value: W.S.LOT1300001/12/010 (New Usage), Comments:

Chemical Name: Ortho-Phosphoric Acid

Batch No	1F2EFRG21	Expiry Date	01-05-2014
Qty. Value	2.9 mL	Sample Reference No.	F02RM13000030

Other Information: W.S. Field: Chemical - 01, W.S. Value: 7664-38-213002/1/2 (New Usage), Comments: --

Chemical Name: Triethylamine

Batch No	SE2E620289	Expiry Date	30-04-2014
Qty. Value	3 mL	Sample Reference No.	F02RM13000030

Other Information: W.S. Field: Chemical - 02, W.S. Value: 121-44-813001/1/2 (New Usage), Comments: --

Chemical Name: Acetonitrile

Batch No	1LMDERF	Expiry Date	02-05-2014
Qty. Value	26 mL	Sample Reference No.	F02RM13000030

Other Information: W.S. Field: Chemical - 03, W.S. Value: 67-64-213001/1/1 (New Usage), Comments: --

Instrument Name: Sonicator(32SON-20)

Calibrated On	08-05-2013	Calibration Due Date	08-05-2014
Used From	07-05-2013 16:00	Used UpTo	07-05-2013 16:10

Other Information: Used For: Assay, Sample Reference No.: F02RM13000030 W.S. Field: Sonicator ID.No 01, W.S. Value: 10000060 (New Usage), Comments:

Refer GTP No. : GP032

Phosphoric acid (2.45 g/L H3PO4) :

Diluted 2.9 ml (CHQTY32) of phosphoric acid to 2000 ml (EWS122) with water and adjusted to pH 3.23 (EDAP23) with 3 mL Triethylamine (CHQTY33).

Printed by: Ajay.Bhushod

Printed on: 10-05-2013 19:13

Page No.: 31 of 35

Note : This document has been generated electronically and is valid without signature.

Format No.

RAW DATA SHEET (Raw Material)

Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Mobile phase:

- 1) **26 ml** (CHQTY34) of Acetonitrile, and **1740 mL** (EWS123) of Phosphoric acid (2.45 g/L H₃PO₄) taken and mixed.
- 2) Filtered the above solution through **0.45 µm** (EWS124) membrane filter.
- 3) Degassed in a Sonicator for **10** minutes (EWS125).

Standard solution -I:

46.8mg(WSQTY02)of the Ciprofloxacin hydrochloride CRS/WS accurately weighed and transferred into a **100mL**(EWS126)volumetric flask, dissolved and diluted to volume with the mobile phase and mixed.

Standard solution -II:

0.05082mg(WSQTY03)of the Ciprofloxacin hydrochloride CRS/WS accurately weighed and transferred into a **100mL**(EWS127)volumetric flask, dissolved and diluted to volume with the mobile phase and mixed.

Test solution:

50mg(EDAP24)of the sample accurately weighed and transferred into a **100mL**(EWS128)volumetric flask, dissolved and diluted to volume with the mobile phase and mixed.

Procedure:

10µL(EWS129)injected separately of the Reference solution (A)-I and Reference solution (A)-II , Test solution, Reference solution (A)-II (as a Bracketing standard) into the liquid chromatograph and the recorded the chromatograms.

Printed by: **Ajay.Bhushod**Printed on: **10-05-2013 19:13**Page No.: **32 of 35****Note : This document has been generated electronically and is valid without signature.****Format No.**

RAW DATA SHEET
(Raw Material)
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.

Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Similarity factor = 1.00 (EWS130) (Limit between 0.98 and 1.02).
Result: **Complies** (Complies / Does not comply) (EWS131)

 Relative standard deviation for Ciprofloxacin peak from standard solution -2 : **0.50**

Old Value: 0.86 %	Reasons: Typo Error	Changed By: Rajesh Kumar. Alubilli 08-05-2013 16:38
-------------------	---------------------	-----------------------------------------------------

 (NMT 0.85 %)(EWS132)

Bracketing system suitability:

 Relative standard deviation for Ciprofloxacin peak from standard solution -2 : **0.50** (NMT 0.85 %)(EWS133)

System Suitability: **Complies** (Complies / Does not comply) (EWS134).

S. No.	Variable	Symbol	TDS Symbol	Value(UOM)
1	Peak area of Ciprofloxacin for Test solution.	A	EDAP32	20275837, 20266129
2	Peak area of Ciprofloxacin for standard solution.	B	EDAP33	18845091
3	Weight of Ciprofloxacin HCl standard taken.	Ws	WSQTY02	46.8 mg
4	Weight of sample taken.	Wt	EDAP34	50.71 mg
5	Potency of standard, calculated as Ciprofloxacin hydrochloride.	P	WSPUR02	93.6 %
6	% Water	W	EDAP31	6.3380 %


Set-1

S. No.	Variable (Symbol)	Value	UOM
1	Peak area of Ciprofloxacin for Test solution. (A)	20275837	
2	Peak area of Ciprofloxacin for standard solution. (B)	18845091	
3	Weight of Ciprofloxacin HCl standard taken. (Ws)	46.8	mg
4	Weight of sample taken. (Wt)	50.71	mg
5	Potency of standard, calculated as Ciprofloxacin hydrochloride. (P)	93.6	%
6	% Water (W)	6.3380	%
	Assay-1 $\frac{((A) * (Ws) * (100) * (P) * (100))}{((B) * (100) * (Wt) * ((100) - (W)))} =$	99.2	%

Set-2

S. No.	Variable (Symbol)	Value	UOM
1	Peak area of Ciprofloxacin for Test solution. (A)	20266129	
2	Peak area of Ciprofloxacin for standard solution. (B)	18845091	
3	Weight of Ciprofloxacin HCl standard taken. (Ws)	46.8	mg
4	Weight of sample taken. (Wt)	50.71	mg
5	Potency of standard, calculated as Ciprofloxacin hydrochloride. (P)	93.6	%

Printed by: **Ajay.Bhushod**Printed on: **10-05-2013 19:13**Page No.: **33 of 35**
Note : This document has been generated electronically and is valid without signature.
Format No.

Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
RAW DATA SHEET (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

6	% Water (W)	6.3380	%
	Assay-2 $\frac{((A) * (Ws) * (100) * (P) * (100))}{((B) * (100) * (Wt) * ((100) - (W)))} =$	99.2	%

S. No.	Variable Reading	Value	UOM
1	Assay-1	99.2	%
2	Assay-2	99.2	%

No. Of Decimals: 1

S. No.	Calculated Value	Limit	Result
1	Minimum: 99.2 %	98.0	Pass
2	Maximum: 99.2 %	102.0	Pass
3	Average: 99.2 %	Lower : 98.0 Upper : 102.0	Pass

Pass Limits(s): Not less than 98.0% and not more than 102.0% of Ciprofloxacin hydrochloride (C17H19CLFN3o3, H2O)

FINAL RESULT: Pass

1	Tested By	Rajesh Kumar. Alubilli	08-05-2013 17:34	---
2	Accepted By	Ajay.Bhushod	09-05-2013 20:50	---

Modified Usage Record Details


Chemical Name:Acetonitrile (Gradient)			
Batch No	R069C13	Expiry Date	03-05-2014
Qty. Value	1.74 L	Sample Reference No.	F02RM13000030
Other Information: W.S. Value: 75-05-813001/1/2(New Usage) , Comments: --			
Reasons:Typo error, Changed By:Rajesh Kumar.Alubilli 07-05-2013 21:24			

Chemical Name:Acetonitrile (Gradient)			
Batch No	R069C13	Expiry Date	03-05-2014
Qty. Value	0.026 L	Sample Reference No.	F02RM13000030
Other Information: W.S. Value: 75-05-813001/1/3(New Usage) , Comments: --			
Reasons:Chemical stock modified, Changed By:Rajesh Kumar.Alubilli 07-05-2013 21:31			

Working Standard Name:Ciprofloxacin Hydrochloride Ph. Eur.(350000089)			
W.S. Lot No.	W.S.LOT1300001	Expiry Date	26-07-2013
Qty. Value	0.05082 g	Purity	93.6 %
Other Information: Sample Reference No.: F02RM13000030, Container Valid Upto: 01-06-2013 W.S. Value: W.S.LOT1300001/12/009(New Usage) , Comments:			
Reasons:Modified, Changed By:Rajesh Kumar.Alubilli 08-05-2013 16:31			

Working Standard Name:Ciprofloxacin Hydrochloride Ph. Eur.(350000089)			
W.S. Lot No.	W.S.LOT1300001	Expiry Date	26-07-2013
Qty. Value	0.04685 g	Purity	93.6 %

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 34 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

Dr. Reddy's Laboratories Ltd. FTO2 Hyderabad.			
RAW DATA SHEET (Raw Material)			
Material Name: Ciprofloxacin Hydrochloride Ph. Eur.			
Material Code	350000089	Specification Id	R0-350000089-00
Batch No.	FBGA00339	STP No.	M0-350000089-00
A.R. No.	F02RM13000030	Inspection Lot. No.	010000830549

Other Information: Sample Reference No.: F02RM13000030, Container Valid Upto: 01-06-2013 W.S. Value: W.S.LOT1300001/12/008(New Usage) , Comments: Reasons:Wrong Selection of UOM, Changed By:Rajesh Kumar.Alubilli 08-05-2013 16:44					
Working Standard Name:Ciprofloxacin Hydrochloride Ph. Eur.(350000089)					
W.S. Lot No.	W.S.LOT1300002	Expiry Date	01-05-2014		
Qty. Value	50 mg	Purity	93.6 %		
Other Information: Sample Reference No.: F02RM13000030, Container Valid Upto: 09-05-2013 W.S. Value: W.S.LOT1300002/1/001(New Usage) , Comments: Reasons:Typo, Changed By:Rajesh Kumar.Alubilli 08-05-2013 16:46					
Working Standard Name:Ciprofloxacin Hydrochloride Ph. Eur.(350000089)					
W.S. Lot No.	W.S.LOT1300002	Expiry Date	01-05-2014		
Qty. Value	46 mg	Purity	93.6 %		
Other Information: Sample Reference No.: F02RM13000030, Container Valid Upto: 09-05-2013 W.S. Value: W.S.LOT1300002/1/002(New Usage) , Comments: Reasons:Typo, Changed By:Rajesh Kumar.Alubilli 08-05-2013 16:47					
Working Standard Name:Ciprofloxacin Hydrochloride Ph. Eur.(350000089)					
W.S. Lot No.	W.S.LOT1300002	Expiry Date	01-05-2014		
Qty. Value	48 mg	Purity	93.6 %		
Other Information: Sample Reference No.: F02RM13000030, Container Valid Upto: 09-05-2013 W.S. Value: W.S.LOT1300002/1/003(New Usage) , Comments: Reasons:--, Changed By:Rajesh Kumar.Alubilli 08-05-2013 17:34					
CDS Report					
SampleSet Name	SampleSet Method	SampleSet StartDate	SampleSet EndDate	System Name	Project Name
Cipro_PhEur_Assay7051302	Cipro_PhEur_Assay7051302	5/8/2013 12:58:00 AM	5/8/2013 6:54:00 AM	32HPL_70	TEST_LIMS
Document(s)					
130000033_19_0					

Printed by: Ajay.Bhushod	Printed on: 10-05-2013 19:13	Page No.: 35 of 35
Note : This document has been generated electronically and is valid without signature.		
Format No.		

Results report

License ID 11007500
Instrument ID 32KFA-07

Instrument sl.No:11166 2013-05-07
8:35:45 PM

Determination

Method Water content (more than 1%)
Determination start 2013-05-07 20:25:53 UTC+5:30
Run number 1
User Rajesh

Sample data

ID1 Ciprofloxacin Ph.Eur
ID2 LIMS TESTING
ID3 Water
Sample size * 0.208 g

End points

KFT Ipol KFT Ipol.1

EP1 2.3560 mL 219.91 s

Results

Water Content 6.3380 %

Calculations

Water Content 6.3380 %
Formula 'KFT Ipol.EP.VOL' * 'CV.KF Factor with water' *
100 / 'MV.Sample size' / 1000
KFT Ipol.EP.VOL 2.3559999465942383
CV.KF Factor with water 5.5955
MV.Sample size 0.208

Analysed By:

Checked By :

Date :

Page 1 of 1

Date :

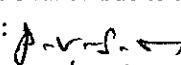
Factory : Dr.Reddy's Laboratories Ltd., Unit-2, Plot No. 110 & 111, S.V. Co-op. Industrial Estate, Bollaram,
Jinnaram (Mdl.), Medak Dist., Andhra Pradesh. INDIA Ph. : 08458 - 279465 & 279466.


CERTIFICATE OF ANALYSIS


Product	: CIPROFLOXACIN HYDROCHLORIDE	Customer name	: Dr.Reddy's Laboratories Ltd (FTO-2)
Batch No.	: ABGH000376	Date of Manufacture	: JANUARY 2013
Batch Quantity	: 279.400 Kg.	Expiry Date	: DECEMBER 2017
A.R.No.	: 40000613586	Date Analysed	: 24.01.2013
Reference	: Ph.Eur / In-house / Customer	Specification No.	: S-08-CW-Ph.Eur/01
Storage	: Store in an airtight container, protected from light.		
Packing condition	: Material is packed in a clear poly bag and tie with nylon strap. Keep this in black poly bag and tie with nylon strap. Keep this in HDPE container.		

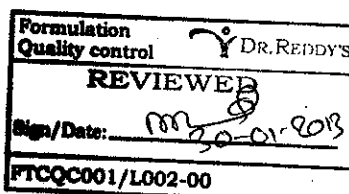
Sl.No.	TEST	RESULT	SPECIFICATION
1.0	Characters		
1.1	Appearance	A pale yellow crystalline powder, slightly hygroscopic.	A pale yellow crystalline powder, slightly hygroscopic.
1.2	Solubility	Complies	Soluble in water, slightly soluble in methanol, very slightly soluble in ethanol, practically insoluble in acetone, in ethyl acetate and in methylene chloride
2.0	Identification		
2.1	IR absorption spectrum	Matches with working standard.	The absorption maxima in the spectrum obtained with the substance being examined correspond in position and relative intensity to those in the spectrum obtained with the Working standard.
2.2	Reaction of chlorides	Positive	To meet the test.
3.0	Appearance of solution	Solution is clear and colour is less than GY ₅	The solution is clear and Not more intensely coloured than that of the Reference Solution GY ₅
4.0	pH of solution S	3.67	3.5 to 4.5
5.0	Impurity A (Fluoroquinolonic acid)	Less than 0.2%w/w	Not more than 0.2 %w/w
6.0	Related substances		
6.1	Ciprofloxacin impurity-C (ethylenediamine compound)	Less than disregard value(0.05%)	Not more than 0.2%w/w
6.2	Ciprofloxacin impurity-D (by-compound A)	Less than disregard value(0.05%)	Not more than 0.2%w/w
6.3	Chloro analog	Less than disregard value(0.05%)	Not more than 0.06%w/w
6.4	Any unknown impurity	Less than disregard value(0.05%)	Not more than 0.06%w/w
6.5	Sum of all impurities	0.1%	Not more than 0.5%w/w

The product CONFORMS to above specifications.

Compiled by : 
Date : 25/01/13

Checked by : 
Date : Page 1 of 2

Head, Quality Control : 
Date : 25/01/13



Factory : Dr.Reddy's Laboratories Ltd., Unit-2, Plot No. 110 & 111, S.V. Co-op. Industrial Estate, Bollaram,
Jinnaram (Mdl.), Medak Dist., Andhra Pradesh. INDIA Ph. : 08458 - 279465 & 279466.

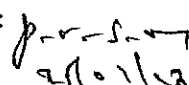
CERTIFICATE OF ANALYSIS

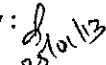
Product	: CIPROFLOXACIN HYDROCHLORIDE	Customer name	: Dr.Reddy's Laboratories Ltd (FTO-2)
Batch No.	: ABGH000376	Date of Manufacture	: JANUARY 2013
Batch Quantity	: 279.400 Kg.	Expiry Date	: DECEMBER 2017
A.R.No.	: 40000613586	Date Analysed	: 24.01.2013
Reference	: Ph.Eur / In-house / Customer	Specification No.	: S-08-CW-Ph.Eur/01
Storage	: Store in an airtight container, protected from light.		
Packing condition	: Material is packed in a clear poly bag and tie with nylon strap. Keep this in black poly bag and tie with nylon strap. Keep this in HDPE container.		
SL.No.	TEST	RESULT	SPECIFICATION
7.0	Heavy metals	Less than 20 ppm	Not more than 20 ppm
8.0	Water	5.6%w/w	Not more than 6.7%w/w
9.0	Sulphated ash	0.04%w/w	Not more than 0.1%w/w
10.0	Assay(on anhydrous basis)	101.0%w/w	Not less than 98.0% and not more than 102.0%w/w
11.0	Residual Solvents by GC-HS		
11.1	Methanol	428 ppm	Not more than 1000 ppm
11.2	Pyridine	Not detected	Not more than 50 ppm
**12.0	Tapped Density	0.49 g/mL	Between 0.35 and 0.55g/mL
*13.0	Particle size 20 ASTM	Nil	Retainers not more than 5.0%w/w
*14.0	Particle size by malvern	D100= 93µm D90= 42µm D50= 17µm	100% should be less than 200µm 90% should be less than 75µm 50% should be less than 30µm


*In-house specifications:-13.0) S-CHIH-012/00. and 14.0)S-08-CH-IH-14/00.

**As per customer specifications:-12.0)CS-CW-009/00.



The product CONFORMS to above specifications.

Compiled by : 
Date : 25/01/13

Checked by : 
Date : 25/01/13

Head, Quality Control : 
Date : 25/01/13

Page 2 of 2

Formulation Quality control	 DR.REDDY'S
REVIEWED	
Sign/Date:  20-01-2013	
FTCQC001/L002-00	

Method Set Name : HPL70_CIPROFLOXACIN PhEur

Instrument ID.No. : 32HPL_70

Project Name : TEST_LIMS

Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4

Acquired By : guest

Column_Number: BL005-01-005

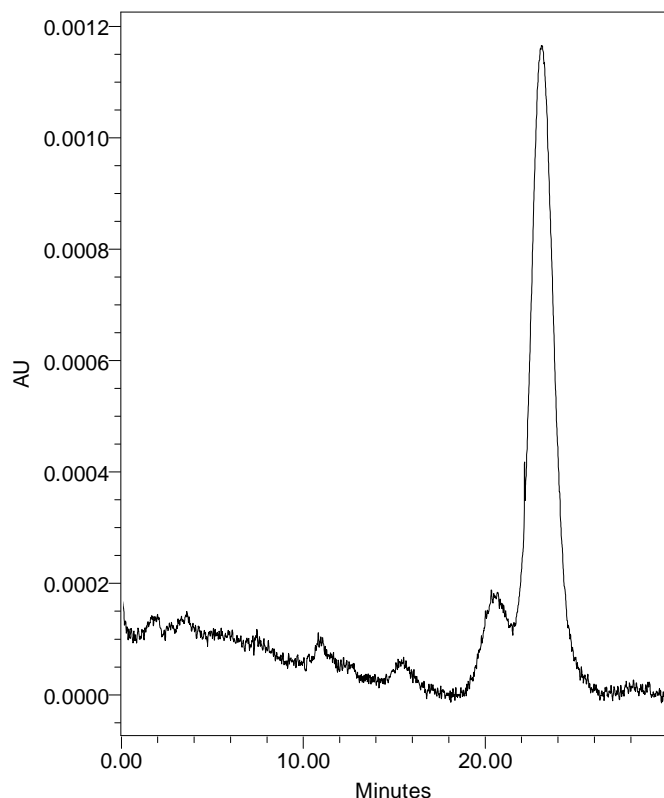
Processed By : guest/Guest

Column_Name: Inertsil ODS 3V

Sample Set Name : Cipro_PhEur_Assay7051302

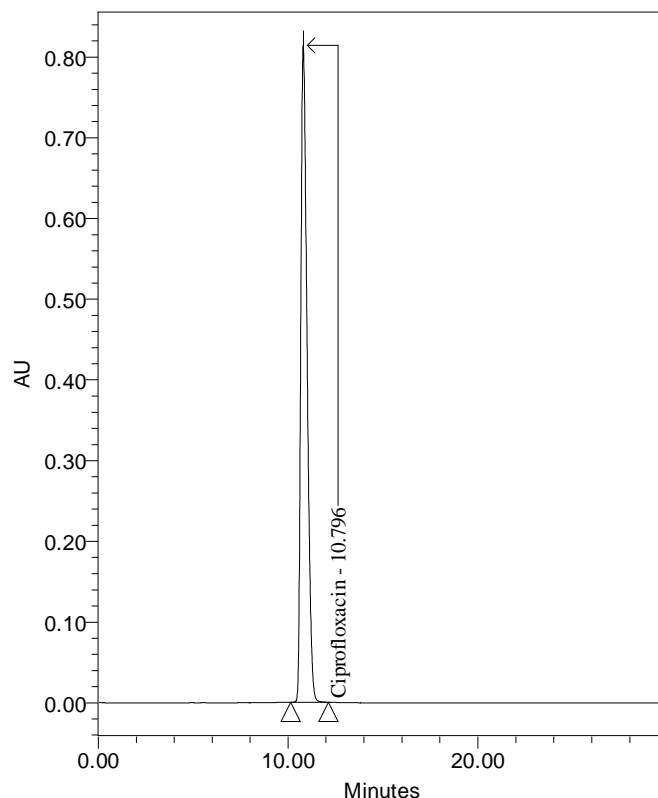
LIMS_ARNO: F02RM13000030

AUTO-SCALED CHROMATOGRAM



SampleName Blank; Vial 1; Run Time 30.00; Injection 1; Date Acquired 5/8/2013 1:00:54 AM IST; Date Processed 5/8/2013 2:32:24 PM IST; Processing Method QC_CIPROFLOXACIN PhEur_AS; Injection Volume 10.00; Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4; Acq Method Set HPL70_CIPROFLOXACIN PhEur; Channel Id 1191; Result Id 1255

AUTO-SCALED CHROMATOGRAM



SampleName Standard-1; Vial 5; Run Time 30.00; Injection 1; Date Acquired 5/8/2013 1:33:14 AM IST; Date Processed 5/8/2013 2:32:25 PM IST; Processing Method QC_CIPROFLOXACIN PhEur_AS; Injection Volume 10.00; Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4; Acq Method Set HPL70_CIPROFLOXACIN PhEur; Channel Id 1195; Result Id 1258

Checked By:

Date :

Method Set Name : HPL70_CIPROFLOXACIN PhEur

Instrument ID.No. : 32HPL_70

Project Name : TEST_LIMS

Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4

Acquired By : guest

Column_Number: BL005-01-005

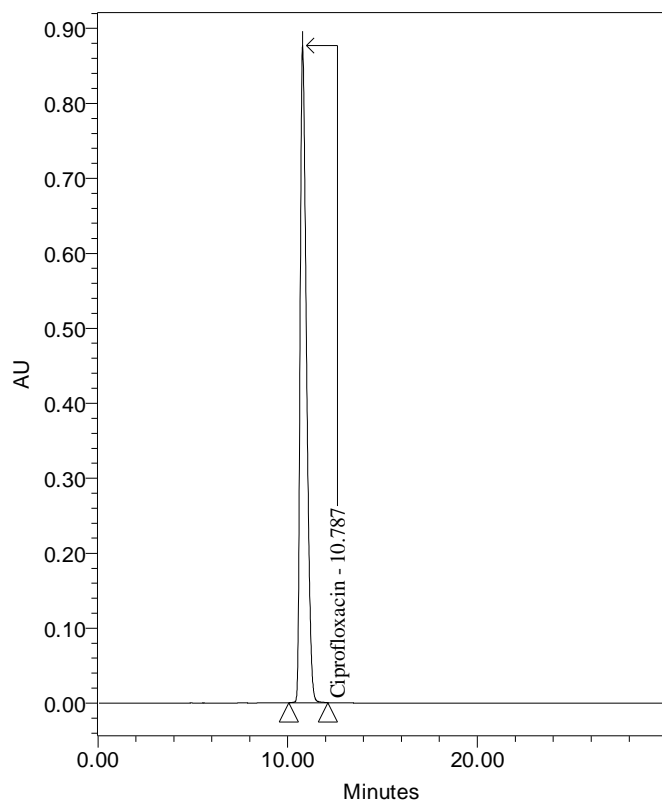
Processed By : guest/Guest

Column_Name: Inertsil ODS 3V

Sample Set Name : Cipro_PhEur_Assay7051302

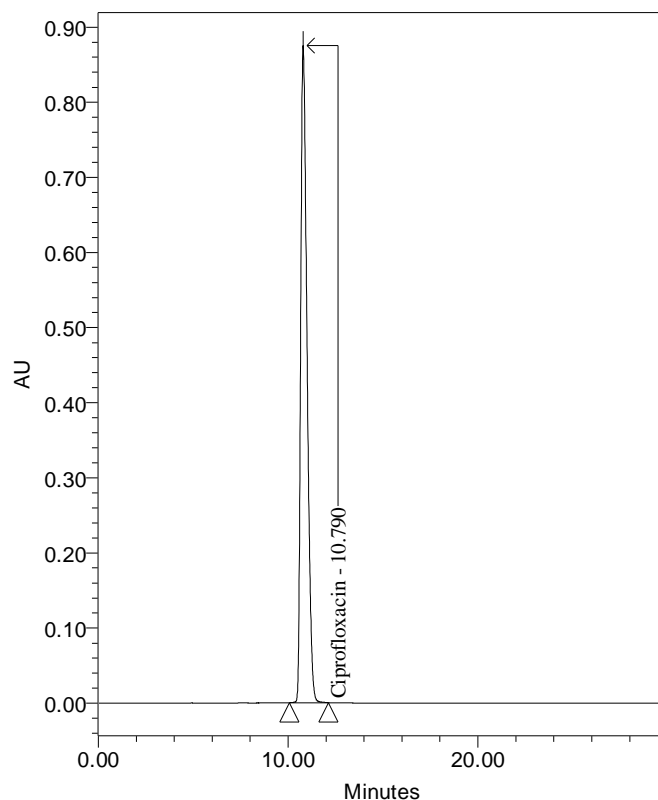
LIMS_ARNO: F02RM13000030

AUTO-SCALED CHROMATOGRAM



SampleName Standard-2; Vial 6; Run Time 30.00; Injection 1;
Date Acquired 5/8/2013 2:05:33 AM IST; Date Processed
5/8/2013 2:32:26 PM IST; Processing Method
QC_CIPROFLOXACIN PhEur_AS; Injection Volume 10.00;
Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4;
Acq Method Set HPL70_CIPROFLOXACIN PhEur; Channel Id
1199; Result Id 1259

AUTO-SCALED CHROMATOGRAM



SampleName Standard-2; Vial 6; Run Time 30.00; Injection 2;
Date Acquired 5/8/2013 2:37:33 AM IST; Date Processed
5/8/2013 2:32:26 PM IST; Processing Method
QC_CIPROFLOXACIN PhEur_AS; Injection Volume 10.00;
Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4;
Acq Method Set HPL70_CIPROFLOXACIN PhEur; Channel Id
1202; Result Id 1260

Checked By:

Date :

Method Set Name : HPL70_CIPROFLOXACIN PhEur

Instrument ID.No. : 32HPL_70

Project Name : TEST_LIMS

Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4

Acquired By : guest

Column_Number: BL005-01-005

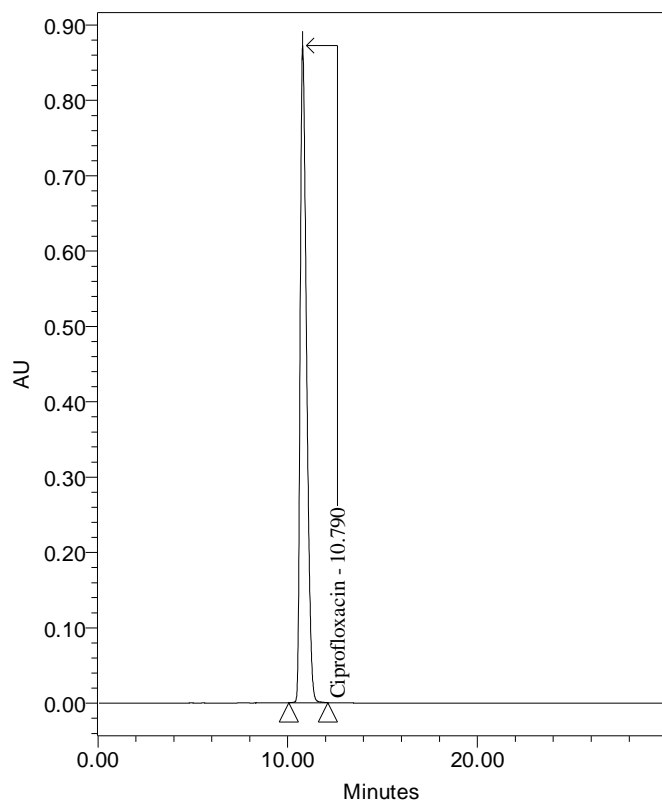
Processed By : guest/Guest

Column_Name: Inertsil ODS 3V

Sample Set Name : Cipro_PhEur_Assay7051302

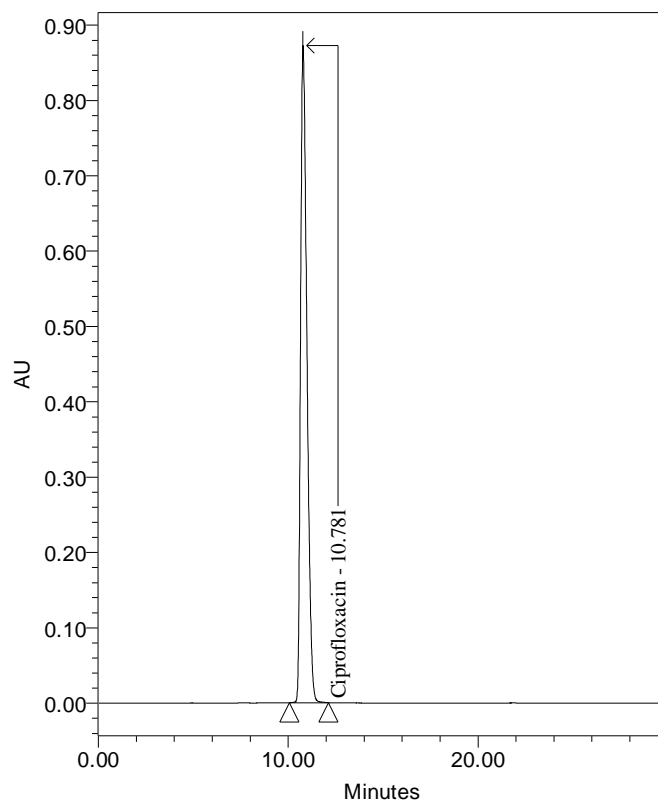
LIMS_ARNO: F02RM13000030

AUTO-SCALED CHROMATOGRAM



SampleName Standard-2; Vial 6; Run Time 30.00; Injection 3;
Date Acquired 5/8/2013 3:09:32 AM IST; Date Processed
5/8/2013 2:32:27 PM IST; Processing Method
QC_CIPROFLOXACIN PhEur_AS; Injection Volume 10.00;
Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4;
Acq Method Set HPL70_CIPROFLOXACIN PhEur; Channel Id
1205; Result Id 1261

AUTO-SCALED CHROMATOGRAM



SampleName Standard-2; Vial 6; Run Time 30.00; Injection 4;
Date Acquired 5/8/2013 3:41:34 AM IST; Date Processed
5/8/2013 2:32:27 PM IST; Processing Method
QC_CIPROFLOXACIN PhEur_AS; Injection Volume 10.00;
Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4;
Acq Method Set HPL70_CIPROFLOXACIN PhEur; Channel Id
1208; Result Id 1262

Checked By:

Date :

Method Set Name : HPL70_CIPROFLOXACIN PhEur

Instrument ID.No. : 32HPL_70

Project Name : TEST_LIMS

Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4

Acquired By : guest

Column_Number: BL005-01-005

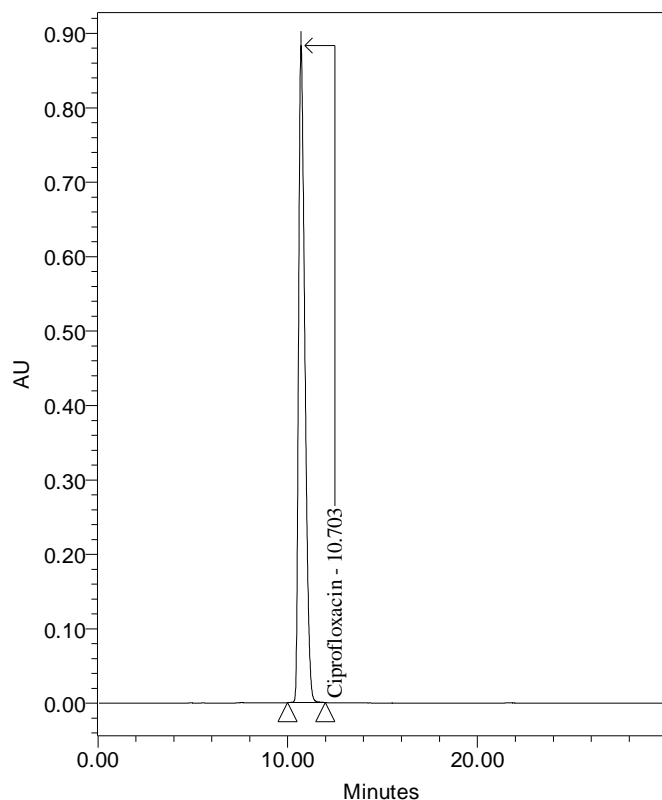
Processed By : guest/Guest

Column_Name: Inertsil ODS 3V

Sample Set Name : Cipro_PhEur_Assay7051302

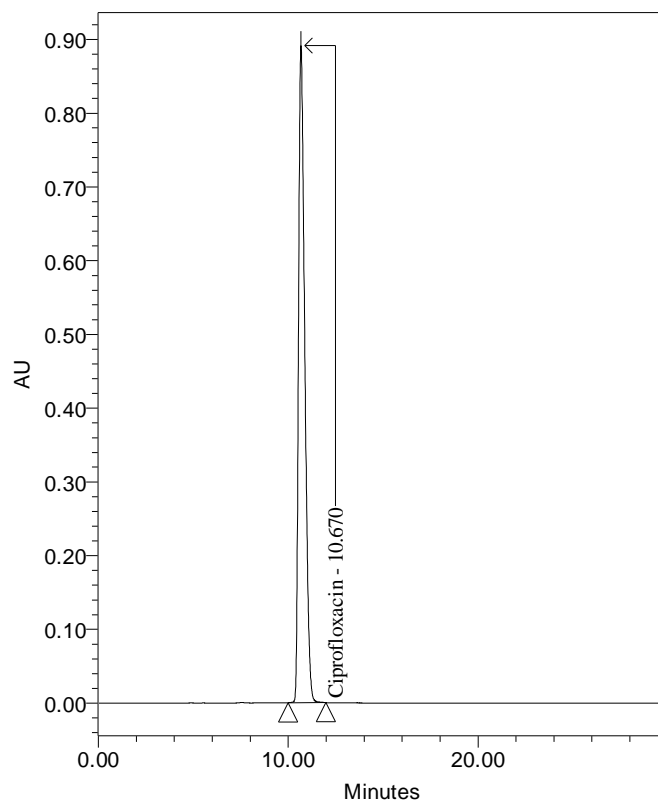
LIMS_ARNO: F02RM13000030

AUTO-SCALED CHROMATOGRAM



SampleName Standard-2; Vial 6; Run Time 30.00; Injection 5;
Date Acquired 5/8/2013 4:13:34 AM IST; Date Processed
5/8/2013 2:32:28 PM IST; Processing Method
QC_CIPROFLOXACIN PhEur_AS; Injection Volume 10.00;
Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4;
Acq Method Set HPL70_CIPROFLOXACIN PhEur; Channel Id
1211; Result Id 1263

AUTO-SCALED CHROMATOGRAM



SampleName Standard-2; Vial 6; Run Time 30.00; Injection 6;
Date Acquired 5/8/2013 4:45:32 AM IST; Date Processed
5/8/2013 2:32:29 PM IST; Processing Method
QC_CIPROFLOXACIN PhEur_AS; Injection Volume 10.00;
Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4;
Acq Method Set HPL70_CIPROFLOXACIN PhEur; Channel Id
1214; Result Id 1264

Checked By:

Date :

Method Set Name : HPL70_CIPROFLOXACIN PhEur

Instrument ID.No. : 32HPL_70

Project Name : TEST_LIMS

Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4

Acquired By : guest

Column_Number: BL005-01-005

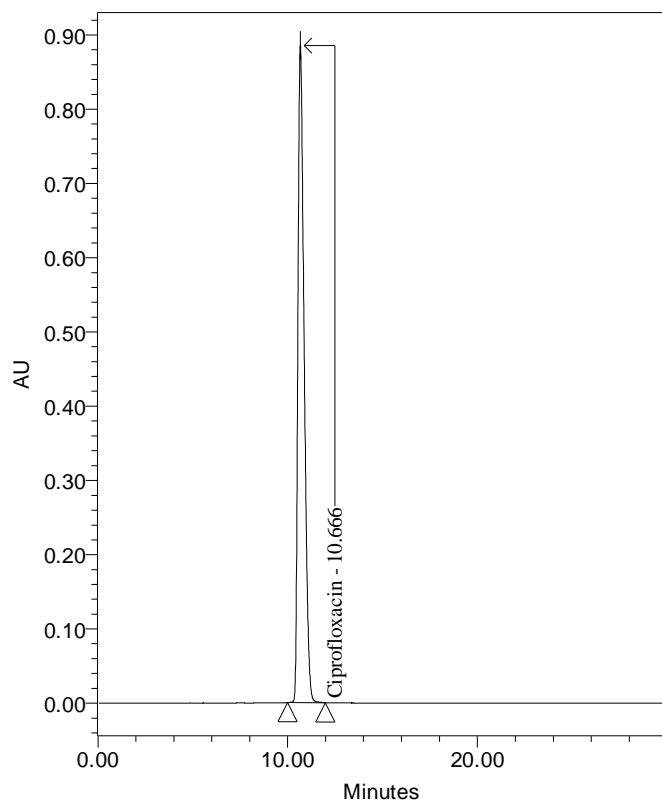
Processed By : guest/Guest

Column_Name: Inertsil ODS 3V

Sample Set Name : Cipro_PhEur_Assay7051302

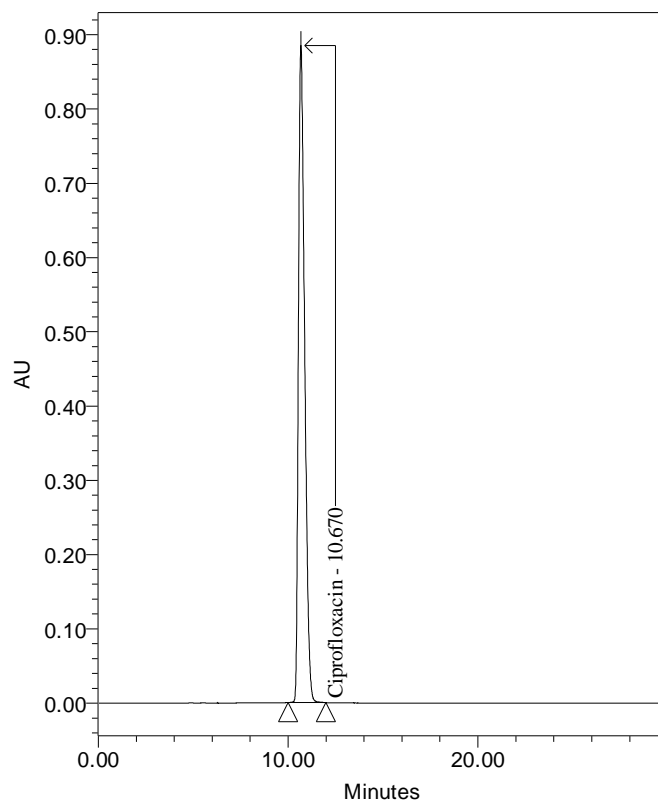
LIMS_ARNO: F02RM13000030

AUTO-SCALED CHROMATOGRAM



SampleName Smp_FBG00339_1; Vial 7; Run Time 30.00;
Injection 1; Date Acquired 5/8/2013 5:17:54 AM IST; Date
Processed 5/8/2013 2:32:29 PM IST; Processing Method
QC_CIPROFLOXACIN PhEur_AS; Injection Volume 10.00;
Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4;
Acq Method Set HPL70_CIPROFLOXACIN PhEur; Channel Id
1218; Result Id 1265

AUTO-SCALED CHROMATOGRAM



SampleName Smp_FBG00339_1; Vial 7; Run Time 30.00;
Injection 2; Date Acquired 5/8/2013 5:49:59 AM IST; Date
Processed 5/8/2013 2:32:30 PM IST; Processing Method
QC_CIPROFLOXACIN PhEur_AS; Injection Volume 10.00;
Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4;
Acq Method Set HPL70_CIPROFLOXACIN PhEur; Channel Id
1221; Result Id 1266

Checked By:

Date :

Method Set Name : HPL70_CIPROFLOXACIN PhEur

Instrument ID.No. : 32HPL_70

Project Name : TEST_LIMS

Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4

Acquired By : guest

Column_Number: BL005-01-005

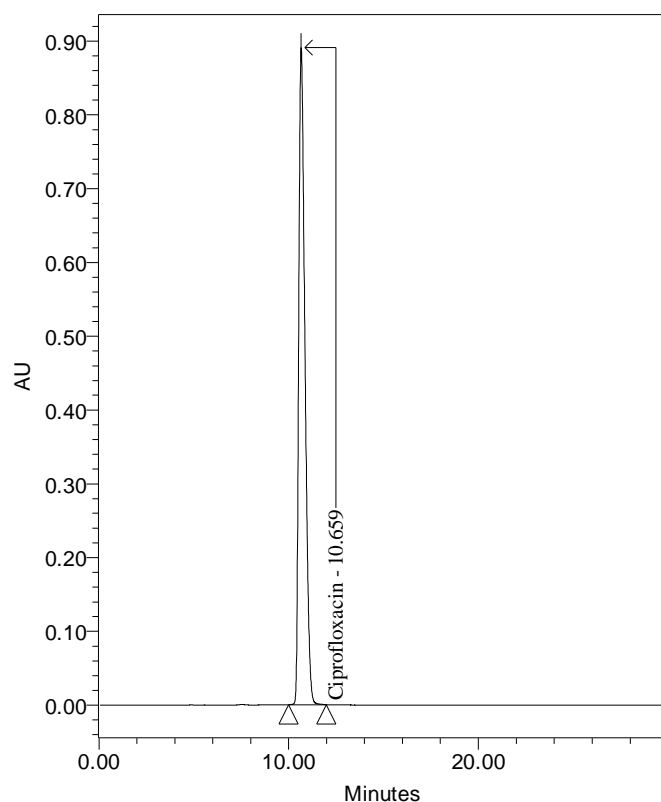
Processed By : guest/Guest

Column_Name: Inertsil ODS 3V

Sample Set Name : Cipro_PhEur_Assay7051302

LIMS_ARNO: F02RM13000030

AUTO-SCALED CHROMATOGRAM



SampleName B.STD(Standard-2); Vial 6; Run Time 30.00;
Injection 1; Date Acquired 5/8/2013 6:22:18 AM IST; Date
Processed 5/8/2013 2:32:30 PM IST; Processing Method
QC_CIPROFLOXACIN PhEur_AS; Injection Volume 10.00;
Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4;
Acq Method Set HPL70_CIPROFLOXACIN PhEur; Channel Id
1225; Result Id 1267

Component Summary Table
Name: Ciprofloxacin

	SampleName	Name	Vial	Inj	RT	Area
1	Blank	Ciprofloxacin	1	1	10.700	
2	Standard-1	Ciprofloxacin	5	1	10.796	18845091
3	Standard-2	Ciprofloxacin	6	1	10.787	20446035
4	B.STD(Standard-2)	Ciprofloxacin	6	1	10.659	20394059

Checked By:

Date :

Method Set Name : HPL70_CIPROFLOXACIN PhEur

Instrument ID.No. : 32HPL_70

Project Name : TEST_LIMS

Processed Channel Descr. MWD AU Ch 1 Sample 278, Bw 4

Acquired By : guest

Column_Number: BL005-01-005

Processed By : guest/Guest

Column_Name: Inertsil ODS 3V

Sample Set Name : Cipro_PhEur_Assay7051302

LIMS_ARNO: F02RM13000030

Component Summary Table

Name: Ciprofloxacin

	SampleName	Name	Vial	Inj	RT	Area
5	Standard-2	Ciprofloxacin	6	2	10.790	20434070
6	Standard-2	Ciprofloxacin	6	3	10.790	20436766
7	Standard-2	Ciprofloxacin	6	4	10.781	20439656
8	Standard-2	Ciprofloxacin	6	5	10.703	20407935
9	Standard-2	Ciprofloxacin	6	6	10.670	20436548
10	Smp_FBG00339_1	Ciprofloxacin	7	1	10.666	20275837
11	Smp_FBG00339_1	Ciprofloxacin	7	2	10.670	20266129
Mean					10.73	20238213
Std. Dev.					0.06	494072
% RSD					0.555	2.441

Checked By:

Date :

Page Number: 7 of 7